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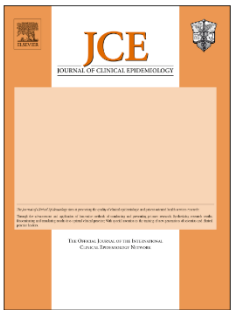

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Abstract

Objective. To assess the impact of recruitment strategy on the baseline characteristics of patients recruited in a randomized controlled trial for treating women with urinary incontinence.

Study Design and Setting. We conducted a cross-sectional analysis of baseline data from an earlier trial. Women were recruited through the media (including social media) or from participating general practices. Baseline characteristics were compared by univariate testing. Logistic regression analysis was performed to study the association between recruitment type and multiple baseline characteristics..

Results. The only differences between recruitment methods were in patient age, with those recruited through the media being significantly older than those recruited through general practice. The mean age difference was 5.0 years (95% confidence interval 2.2–7.9).

Conclusion. Samples recruited through the media and through case identification were largely comparable. Therefore, recruitment through the media may be a viable alternative to recruitment through primary care. This may be especially relevant for research on eHealth treatment for conditions with which patients experience barriers when seeking healthcare.

Keywords

Patient recruitment; Urinary incontinence; eHealth; Primary care; Randomized controlled trial

Running title: Media recruitment versus GP recruitment

1. Introduction

Recruitment in clinical trials is often problematic, with reports indicating that only around 55% of clinical trials succeed in recruiting the prespecified target sample size,[1] and around 11% of all trials involving patients being discontinued because of poor recruitment.[2] This has also been observed in trials in primary care in the Netherlands, where it was shown that almost 40% of projects needed to be extended by at least 50% to obtain the target sample size.[3] [3]When this problem arises, other recruitment strategies may be appropriate, such as recruiting patients via the media, including social media. Indeed, recruitment through (social) media has been found to be cost-effective in studies on mobile health interventions for healthy infant feeding practices,[4] the treatment of heavy-drinking smokers,[5] and weight loss in postmenopausal obese women.[6] However, unequal representation when using different recruitment strategies may lead to the possibility of different baseline characteristics.[7-9] This may have implications for studies on the effectiveness of an intervention and for the generalizability of study results.

We recently conducted a randomized controlled trial (RCT) to assess the non-inferiority of app-based treatment compared to usual care in women with urinary incontinence. In this trial, we had planned to recruit only incident and prevalent cases through general practitioners (GPs).[10] However, despite enough GPs agreeing to participate, we experienced problems because they often recruited no or very few patients. We therefore decided to expand recruitment to include the media, including social media, but we do not know if this sample is comparable to the women who were recruited by GPs. In this research, we aimed to analyze the impact of this change in recruitment strategy on the baseline characteristics of participants in the RCT.

2. Methods

2.1. Study design and recruitment

women. Part of the study involved a pragmatic non-inferiority RCT, for which an extensive description has been published elsewhere.[10] From July 2015 to November 2017 patients were recruited through GPs only, including both incident and prevalent (i.e., non-incident) cases. However, from November 2017 to June 2018, recruitment was done via both GPs and (social) media. All patients gave written informed consent before participating in the study.

Incident and prevalent cases were recruited through 89 participating GPs who agreed to recruit patients for the study. Prevalent cases were approached by letter in 14 of the 30 collaborating practices. The (social) media campaign consisted of the following: interviews in regional newspapers spread through LinkedIn, Facebook, and Twitter; interviews on national and regional radio, as well as local TV; and directed advertisements on Facebook in the study region.

2.2. Baseline characteristics

We collected characteristics during a baseline visit and through an online questionnaire. Medical and gynecological histories were obtained during these visits, and a research physician performed a physical examination to assess pelvic floor activity and prolapse. The online questionnaire assessed the impact of incontinence symptoms (using the ICIQ-UI-SF questionnaire),[11] quality of life (using the EQ-5D-5L, including the EQ-VAS),[12] disease-specific quality of life (using the ICIQ-LUTS-QoL),[13] and the impact of incontinence on sexual functioning (using the PISQ-IR).[14]

2.3. Analyses

Analyses were performed on complete cases with no imputation for missing data because the number of missing values was negligible at baseline. The characteristics of subjects in the two recruitment groups (i.e., GP-recruited and media-recruited cases) were compared by independent t-test or Mann-Whitney U tests for continuous data and by chi-square tests for categorical data, as appropriate.

putative variables were then selected: age, duration of complaints, ICIQ-UI score, type of urinary incontinence (stress or urgency), previous physical therapy for urinary incontinence (yes or no), history of pregnancy (yes or no), and postmenopausal. Multicollinearity between variables was assessed, model fit was assessed by the Hosmer–Lemeshow test and explained variance by the Nagelkerke R^2.

All analyses were performed using IBM SPSS for windows, Version 25.0 (IBM Corp., Armonk, NY), using a two-sided alpha of 0.05. A Bonferroni correction was applied based on 29 tests resulting in an alpha of 0.002.

3. Results

3.1. Trial recruitment

In total, 262 women were included and randomized, of whom 256 (98%) had complete baseline data and were included for analysis. Thereby the trial met its target sample size of 250 women.[10] Because of a higher than expected loss to follow-up 12 additional women were recruited. The recruitment trajectory of the trial is shown in Figure 1. Recruitment of participants through 89 GPs resulted in the inclusion of approximately 4 participants per month, recruitment through the media resulted in the inclusion of approximately 14 participants per month (Figure 1).

3.2. Differences in baseline characteristics

Among the 108 participants recruited through (social) media, 48 indicated that they had heard about the study through traditional media, 38 through social media, and 22 provided no data on the source. Univariate comparisons among the groups showed a difference only for age (Table 1, t = -3.495, df = 254, p=0.001). The mean difference in age was 5.0 years (95% confidence interval 2.2-7.9).

methods

	GP recruited	Media recruited	p-value
	N = 148	N = 108	
Allocation: intervention/care as usual, N	75/73	54/54	
General characteristics			
Age (Mean ± SD)	50.1 ± 11.1	55.2 ± 11.8	0.001
BMI (Mean ± SD)	28.0 ± 5.4	27.2 ± 5.2	0.230
Gynecological history and status			
Postmenopausal status, N (%)			
Not postmenopausal	80 (54.1)	47 (43.5)	0.246
Postmenopausal	63 (42.6)	56 (51.9)	
Unknown due to anticonception	5 (3.4)	5 (4.6)	
Number of pregnancies, N (%)			
0	15 (10.1)	10 (9.3)	0.832
1	15 (10.1)	14 (13.0)	
2	54 (36.5)	42 (38.9)	
≥3	64 (43.2)	42 (38.9)	
Number of vaginal deliveries, N (%)			
0	25 (16.9)	17 (15.7)	0.882
1	21 (14.2)	15 (13.9)	
2	60 (40.5)	49 (45.4)	
≥3	42 (28.4)	27 (25.0)	
Hysterectomy, N (%)	14 (9.5)	9 (8.3)	0.756
Other abdominal surgery, N (%)	51 (34.5)	40 (37.0)	0.670
Patient reported feeling of prolapse, N (%)	13 (8.8)	5 (4.6)	0.199
Prolapse (POP-Q stadia), N (%)			
Stadium 0	23 (15.5)	18 (16.7)	0.197
Stadium 1	61 (41.2)	55 (50.9)	
Stadium 2A	64 (43.2)	35 (32.4)	
Pelvic floor functioning, N (%)			
normal	45 (30.4)	38 (35.2)	0.832
Overactive	23 (15.5)	17 (15.7)	
Underactive	79 (53.4)	53 (49.1)	
inactive	1 (0.7)	0 (0.0)	
Incontinence complaints			
Duration of urinary incontinence (years; median|IQR)	7 | 8	9.5 | 15.25	0.077
Urinary incontinence type, N (%)			
Stress incontinence	61 (41.2)	46 (42.6)	0.458
Urgency incontinence	10 (6.8)	12 (11.1)	
Mixed (stress primary)	40 (27.0)	30 (27.8)	
Mixed (urgency primary)	37 (25.0)	20 (18.5)	
Impact of urinary incontinence symptoms (ICIQ-UI SF sum score; mean ± SD)	9.6 ± 3.5	10.2 ± 3.0	0.165

General			
EQ-5D-5L, index score (median|IQR)	0.89 | 0.18	0.89 | 0.18	0.618
EQ-VAS (median|IQR)	80 | 25	80 | 22	0.844
Disease specific			
ICIQ-LUTS-QoL (median|IQR)	31 | 10	32 | 8.75	0.059
urinary incontinence and sexuality			
PISQ-IR			
Sexually active, N (%)	118 (79.7)	74 (68.5)	0.041
Not sexually active	N = 30	N = 34	
NSA-PR	50 | 50	50 | 50	0.650
NSA-CS	27.8 |66.7	16.7 | 55.6	0.504
NSA-GQ	28.6 | 50	32.1 | 35.7	0.951
NSA-CI	11.1| 36.1	5.6 | 44.4	0.983
Sexually active	N = 118	N = 74	
SA-PR	88.8 | 22.2	77.8 | 33.3	0.278
SA-CS	66.6 | 16.7	66.6 | 10.4	0.910
SA-GQ	40 | 26.7	47 | 28.3	0.166
SA-CI	75 | 8.3	75 | 16.7	0.987
SA-AO	56.3 | 18.8	56.3 | 13	0.481
SA-D	50 | 83.3	50 | 16.7	0.217

*statistically significant after Bonferroni correction (alpha after correction = 0.002)

Table 2 shows the results of the logistic regression analysis. Duration of symptoms was transformed because of a skewed distribution using a natural log transformation. Again age was the only factor that differed between recruitment types.

Table 2. Results of logistic regression analysis testing the association between multiple baseline

	Odds ratio for media recruitment OR (95% CI)	P-value
Age	1.06 (1.03-1.10)	0.001*
Postmenopausal status (ref = not menopausal)		
Postmenopausal	0.56 (0.24-1.33)	0.188
Unknown due to anticonception	1.10 (0.28-4.28)	0.895
Previous pregnancy (ref = no previous pregnancy)	0.77 (0.29-2.01)	0.589
Duration of symptoms (natural log transformation)	1.26 (0.95-1.67)	0.104
Type of incontinence (ref = stress incontinence)	0.76 (0.40-1.43)	0.397
ICIQ-UI-SF baseline score	1.06 (0.97-1.15)	0.207
Previous physical therapy (ref = no physical therapy)	0.51 (0.28-4.28)	0.037
Nagelkerke R^2 = 0.122		
Hosmer and Lemeshowtest = 0.467		

*statistically significant after Bonferroni correction (alpha after correction = 0.002)

4. Discussion

4.1. Summary of results.

Different recruitment strategies can lead to differences in the characteristics of recruited samples. In our RCT of app-based treatment for urinary incontinence, however, samples recruited by two different strategies were largely comparable. Indeed, there was only a difference in age between cases recruited through GPs and cases recruited through (social) media, with the latter group being

combining multiple baseline characteristics, age again was the only factor that differentiation between recruitment types.

4.2. Literature.

In this study, recruitment through the media comprised both traditional media (e.g., newspaper items, radio, and TV) and social media (e.g., Facebook, LinkedIn, and Twitter). Although recruitment through the media was almost evenly distributed between traditional and social media, we were unable to compare the two. In a review that compared recruitment by social media to that by other methods, only a few studies were reported to have compared the characteristics of patients recruited by traditional and social media.[15] Of note, it was reported that the relationship with age was contradictory between studies. Two studies of smoking cessation found that subjects recruited through social media were younger than those recruited with traditional methods, such as flyers, newspapers, and word of mouth.[9,16] By contrast, a study on lung cancer screening indicated that there were no age differences between subjects recruited through social media and through newspaper advertisements.[17] In some studies included in the review,[15] differences were found in ethnicity, education level, and socioeconomic status between methods, and it should be noted that these variables were not included in the present study. The authors concluded that recruitment via social media typically led to samples that were not comparable to those recruited by other methods.[15] Nevertheless, this judgment was made on the basis of a difference on a single variable. Another systematic review concluded that recruitment through Facebook led to a group of participants that was representative of traditional methods except for a few minor differences.[18] One difference was that participants were generally younger when recruited through Facebook.

To date, no reviews have identified studies that have directly compared participant characteristics after recruitment through a GP or social media.[15] Indeed, there is only sparse literature comparing recruitment by GPs with recruitment by traditional media. One study of

recruitment methods.[19] Active recruitment (i.e., directly contacting a subject from a defined subject pool) was used in our recruitment of GP cases, whereas passive recruitment (i.e., a general invitation to participate) was used in our media recruitment.[20] The comparison between such active and passive methods of recruitment has been made in other studies. In those focusing on lifestyle interventions, for example, subjects recruited through passive methods had more favorable lifestyles, indicating a selection bias.[20,21] Such bias, indicating a tendency to attract subjects with certain health or disease statuses, was not apparent in the present study.

[22]

4.3. Interpretation of outcomes

The average age difference of 5 years between our study groups was significant, and this finding is particularly relevant for incontinence, which is an age-related condition in which severity increases with age.[23] Therefore, including (social) media cases with a higher age may potentially have resulted in including women with more severe symptoms, yet this was not observed and disease symptoms were comparable between groups. A reason for the difference in age between (social) media cases and GP cases may be that older women do not seek help for their complaints because they assume that the symptoms reflect normal aging.[24] Thus, the older ages among women recruited through the media may reflect a successful public health campaign that accessed more women with erroneous beliefs.

4.4. Limitations

A limitation of this research is that it was not powered for the analyses performed, because the primary aim was to look at the effectiveness of app-based treatment compared to care-as-usual. Another limitation is that relevant comparison variables may not have been measured (e.g., socioeconomic status) because the study was not designed to compare recruitment methods.

4.5. Implications of changing recruitment strategy

(social) media for recruitment was to speed up the recruitment process, the increase in recruitment rate emphasizes that recruitment through (social) media has an important role for women with incontinence, which is a frequent problem for which many women do not seek care despite having significant symptom burdens.[24] Improved attention through (social) media may overcome the barriers to seeking health care for women who experience this problem. However, using such a recruitment strategy changes the target population from women that visit their GP for UI, to also include women that are not in GP records with UI complaints.

4.6. Conclusions

In conclusion, despite a difference in age, recruitment through the media rather than by case identification during consultations had no major impact on the sample that was finally recruited for our study. This will be of particular relevance to future studies given that only a small proportion of women with urinary incontinence seek care through routine consultations,[25,26] which potentially limits sample sizes or necessitates prohibitively long study periods. Recruitment through the media, including social media, could therefore serve as an alternative recruitment strategy to increase study engagement.

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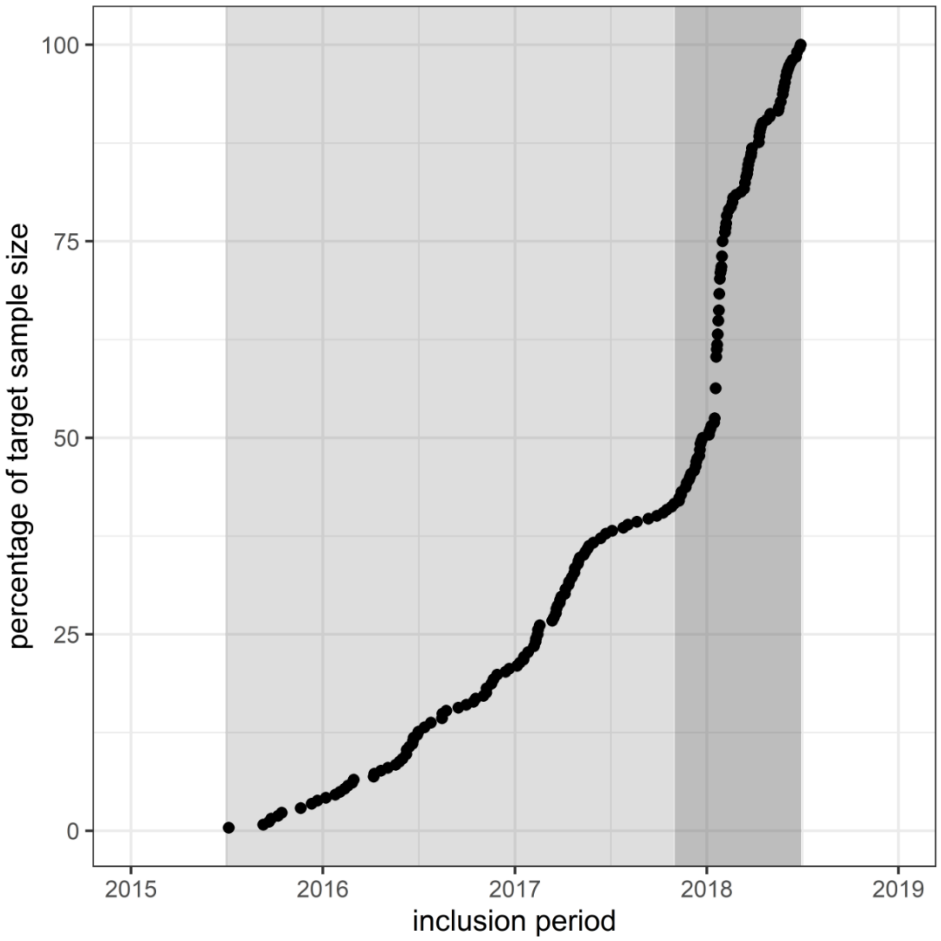
Figure captions:

Figure 1. Recruitment trajectory of the trial over time. During the first part of the trial participants were recruited through GPs only (light gray area). During the last part of the trial participants were also recruited through the media (dark gray area.


100
75
50
25
0
percentage of target sample size
2015
2016
2017
2018
2019
inclusion period

Abstract accepted for ICS annual conference, September 2019

Hypothesis/aims of the study

Only around half of all clinical trial succeed in recruiting enough participants to meet the originally specified sample size. In case of problematic recruitment, other strategies may be chosen, such as recruiting participants through social media or lay press. However, applying a different recruitment strategy may lead to sampling bias. This may impair the interpretation of the intervention outcomes and the generalizability of the study results.

We conducted a Randomized Controlled Trial (RCT) comparing an app-based treatment for women with urinary incontinence with usual primary care. We recruited both incident and prevalent cases through general practitioners, but experienced sincere problems with recruitment. We therefore decided to expand to (social) media approaches. To allow a proper interpretation of the generalizability of the outcomes, we analyzed the impact of recruitment strategy on the baseline characteristics of the participants in this RCT.

Study design, materials and methods

We are performing a mixed-methods study on the impact of a mobile application for urinary incontinence in adult women. Part of the study is a pragmatic randomized-controlled non-inferiority trail. Patients were only recruited through GPs from July 2015 to June 2018 (both incident and prevalent cases) and through both (social) media and GPs from November 2017 to June 2018.

The (social) media campaign consisted of interviews in regional newspapers spread through LinkedIn, Facebook and Twitter, interviews on national and regional radio and local broadcasting and directed advertisements on Facebook in the study region.

We collected characteristics through an online questionnaire, and during a baseline visit, consisting of medical history taking and a physical examination. The questionnaire assessed impact of incontinence symptoms (ICIQ-UI-SF questionnaire), quality of life (the EQ-5D-5L including the EQ-VAS) and disease specific quality of life (ICIQ-LUTS-QoL).

Analyses were performed on complete cases without imputation of missing data, because the number of missing values on baseline was expected to be limited.

Baseline characteristics of subjects in the three recruitment groups (incident cases, prevalent cases

correction was applied to control for multiple comparisons. In case of a significant difference, a post-hoc test was performed to identify which recruitment groups differed.

Results

Two-hundred-sixty-two subjects were randomized of which 256 (98%) subjects had complete baseline data and were included for this analysis. Of these, 120 were incident cases, 28 were prevalent cases and 108 were recruited through (social) media. Univariate between group comparisons showed only difference for age (Table 1, $F=9.0$, $df=2$, $p<0.001$). Post-hoc analyses showed that patients recruited through (social) media were significantly older than incident cases (mean difference 6.1 years (95% CI 2.5 to 9.7)) but that prevalent cases did not differ from the other two groups. No differences were found between groups in BMI, gynecological history and status, incontinence complaints, duration of incontinence and quality of life.

Interpretation of results

In this RCT on treatment of female urinary incontinence we found that samples recruited with different strategies were to a large extend comparable. Women included through the social media campaign were considerably older than women invited through general practices. However, this difference in age was not reflected in differences in age related outcomes such as symptom severity, type of urinary incontinence, menopausal status and quality of life.

Concluding message

Using different methods for recruiting women with urinary incontinence did not lead to large differences in characteristics of recruited samples in this study. Therefore recruitment through social media may be considered as a good alternative to other methods when recruiting women with urinary incontinence. This may overcome the barrier that many women experience in seeking help for this important health problem.